REMARKS

The Examiner has indicated that claims 7 and 9 are allowed. In the interest of furthering prosecution Claim 10 has been amended as suggested by the Examiner. No new matter has been added.

Rejections under 35 USC § 112

Claim 10 stands rejected under 35 USC §112 first paragraph as lacking enablement. Applicants' respectfully traverse the rejection.

The specification provides objective enablement for the methods of the present claims. For example, as noted on page 2 of the specification, compounds of the present invention are powerful activators of the PPARα and PPARγ isoforms. On account of this activity, these compounds have a considerable hypolipidaemiant and hypoglycaemiant effect. The specification teaches a skilled worker how to measure for PPAR activity. See, for example, page 32 which cites Lehmann et al. (1995, J. Biol. Chem. 270: 12953-12956) and page 32 line 22 to page 33 line 14. Moreover, as discussed on page 2 of the specification the development of atherosclerosis is linked to abnormal levels of lipoproteins in the blood plasma (i.e., dyslipidaemia). This dysfunction is particularly evident in coronary disease, diabetes and obesity.

In any event, the specification also otherwise provides ample guidance as to how to prepare pharmaceutical compositions with the compounds of claim 7 used in the method of claim 10 and how to administer these compositions in the treatment of dyslipidaemia, atherosclerosis or diabetes. See, for example, page 32 which provides a skilled worker with guidance on dosage amounts and various methods of administration. Given the extent of the disclosure provided, it would at most involve routine experimentation if any at all, for one of ordinary skill in the art to treat dyslipidaemia, atherosclerosis or diabetes.

Even absent the specification disclosures discussed above, the rejection is clearly deficient in general under controlling case law. The courts have placed the burden upon the PTO to provide evidence shedding doubt on the disclosure that the invention can be made and used as stated; see, e.g., In re Marzocchi, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971) (holding that how an enablement teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.) The disclosure must be taken in compliance with the enablement requirement of the first paragraph of § 112 unless there is reason to doubt the

objective truth of the statements contained therein. See In re Marzocchi, supra. The final office action does not adequately address why dyslipidaemia, atherosclerosis or diabetes, which are known to be linked to abnormal levels of lipoproteins in the blood plasma, could not be treated by addressing abnormal levels of lipoproteins in the blood. Other than broad conclusory statements no such evidence or reason for doubting Applicants' disclosure has been provided.

Additionally, "the [enablement] requirement is satisfied if, given what they [, those of ordinary skill in the art,] already know, the specification teaches those in the art enough that they can make and use the claimed invention without 'undue experimentation.'" See Amgen v Hoechst Marion Roussel, 314 F.2d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). Using the 13 specific compounds of claim 7 in the claimed method would be routine for those of ordinary skill in the art in view of Applicants' disclosure. Explicitly providing dedicated assays is not necessary to enable the present claims. See, for example, In re Howarth, 654 F.2d 105, 210 U.S.P.Q. 689 (CCPA 1981) ("An inventor need not … explain every detail since he is speaking to those skilled in the art."); In re Gay, 309 F.2d 769, 774, 135 U.S.P.Q 311 (CCPA 1962) ("Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be.")

There is no requirement that an applicant provide any working examples relating to the treatment of disease to satisfy the statute. See, for example, In re Angstadt, 537 F.2d at 502-03, 190 USPQ 214 (CCPA 1976). The MPEP also agrees by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

No evidence has been presented that the 13 specific compounds of claim 10 would not be effective in treating dyslipidaemia, atherosclerosis or diabetes. The specification clearly enables a skilled worker to treat dyslipidaemia, atherosclerosis or diabetes by administering to a patient in need thereof an effective amount of one of the 13 specific compounds according to claim 7. No undo experimentation would be required.

Thus, it is respectfully requested that the rejections under 35 USC §112 be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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